K024243

JUN 2 0 2003

510(k) Summary

Category:	Comments
Sponsor:	Fox Hollow Technologies Inc. 300 Saginaw Drive Redwood City, CA 94063
Correspondent:	Suzon Lommel Vice President Regulatory Affairs/Quality Assurance 300 Saginaw Drive Redwood City, CA 94063

Contact Numbers:	Phone: 650-568-2521	Fax: 650-364-2315
Device Common Name:	Catheter, Atherectomy, Peripheral	
Device Proprietary Name:	ReFORM™ Peripheral Catheter System	
Device Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal	
Device Classification:	Device: Catheter, Angioplasty, Peripheral, Transluminal or Device: Catheter, Peripheral, Atherectomy Product Code: MCW 510(k) exempt: No	
Predicate Device	Simpson Peripheral Atherocath	
Predicate Device Manufacturer(s)	Devices for Vascular Intervention	
Predicate Device Reference(s)	K871011, K874706, K881088, K883346	
Predicate Device Proprietary Name(s)	Simpson Peripheral Atherocath	
Predicate Device Classification Name(s)	Catheter, Angioplasty, Peripheral, Transluminal	
Predicate Device Classification(s)	Product Code: LIT	

Date Summary Was Prepared: Wednesday, December 18, 2002.

Description of the Device: The ReFORM Peripheral Catheter System consists of two major components which are packaged separately but used together during atherectomy procedures. The two components are the ReFORM Peripheral Catheter and the ReFORM Cutter Driver.

The ReFORM Peripheral Catheter is comprised of a long, low-profile shaft at the end of which is a small mechanical cutter. The catheter is a monorail design which allows a single operator to insert and remove the device from the patient while maintaining guidewire position. A Cutter Driver controls the actuation of the cutting element. Excision of atheroma from the vessel is accomplished by a small spinning cylindrical blade contained within a cylindrical housing. Once the catheter is tracked to the target lesion, the tip is deflected, moving the cutter against the lesion. As the cutting blade spins, the device is advanced through

the lesion, "shaving" plaque from the vessel wall. As the tissue is cut, it enters the device through a small opening just distal to the blade and is captured in the catheter tip and removed from the patient.

Intended Use: The intended use of the ReFORM Peripheral Catheter System is identical to the approved indication for the Simpson Peripheral Atherocath™, which was found to be substantially equivalent to the Dotter Transluminal Dilatation Catheter, Percutaneous Transluminal Angioplasty Balloon Dilatation Catheters and Intraluminal Arterial Strippers (K871011 – May 14, 1987). Both the ReFORM Peripheral Catheter System and the Atherocath™ are designed for atherectomy of the peripheral vasculature and neither is intended for use in the coronary or carotid vasculature.

Technological Characteristics: ReFORM Peripheral Catheters consist of a braided drive shaft inside a Pebax/Nylon outer shaft, connecting to the cylindrical cutter and cylindrical cutter housing. The soft, flexible tip also provides an area for tissue collection. At the end of each cutting pass, the cutter advances into the soft tip "packing" tissue into the nosecone. The cutter housing is radiopaque due to plating with platinum which allows it to serve as an angiographic marker for easy positioning of the cutter blade within the lesion. ReFORM Peripheral Catheter System configurations covered under the subject 510(k) Premarket Notification include 7 F and 8 F sheath compatible diameter catheters in lengths of 135 cm and110 cm respectively.

Comparison to Predicate Devices: As compared to the predicate device the ReFORM Peripheral Catheter System has the same indications for use, the same general method of operation, is for single use, is provided sterile, is comprised of the same general patient contact materials, and has the same device classifications and device codes.

Summary of the Non-Clinical Performance Data: Performance testing to support the safety and efficacy of the ReFORM Peripheral Catheter System has been performed and presented in detail in the body of this 510(k). In addition, testing has been performed comparing the performance of the ReFORM Peripheral Catheter System with the DVI Simpson Atherocath™.

Clinical Data: As compared to the predicate devices the ReFORM Peripheral Catheter System has the same indications for use, the same general method of operation, is also for single use, is provided sterile, is comprised of the same general patient contact materials, and has the same device classifications and device codes therefore we believe minimal new clinical data is required. Animal test data and human clinical study safety data are included in the body of the submission.

Summary of the Non-clinical General Data: All applicable testing conformed to the requirements of 21 CFR Part 58 (Good Laboratory Practices) specifically, tests included biocompatibility, reliability, sterility and functional performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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FoxHollow™ Technologies
c/o Ms. Suzon Lommel
Vice President
Regulatory Affairs/Quality Assurance
300 Saginaw Drive
Redwood City, California 94063-4743

Re: K024243
Trade Name: Reform Peripheral Catheter System
Regulation Number: 21 CFR § 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: II (two)
Product Code: MCW
Dated: April 1, 2003
Received: April 3, 2003

Dear Ms. Lommel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement:

Ver. 3 - 4/24/96
Applicant: Fox Hollow Technologies, Inc.
510(k) Number (if known): _____
Device Name: FHT Peripheral Debulking System
Indications For Use:

The ReFORM Peripheral Catheter System is intended for use in atherectomy of the peripheral vasculature. The catheter **is not** intended for use in the coronary or carotid vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Prescription Use Only

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K022243